

NOV 28 2004

**NOTIFICATION PURSUANT TO  
SECTION 6 OF DSHEA  
AND 21 CFR § 101.93**

3 2004

This notification is being filed on behalf of Covaxil™ Laboratories, LLC that is the Distributor of the product(s) which bear the statements identified in this notification. Its business address is: 5742 W Harold Gatty Dr. Salt Lake City, Utah 84116. This notification is being made pursuant to Section 6 of DSHEA and Rule 21 C.F.R. § 101.93. The dietary supplement product on whose label or labeling the statements appear is **Estrin-D™**.

The text of each structure-function statement for which notification is now being given is:

- (Statement 1): "Raises resting metabolic rate in menopausal and perimenopausal women."
- (Statement 2): "Boost energy levels and increase stamina in menopausal and perimenopausal women"
- (Statement 3): "Reduces diet fatigue associated with menopausal and perimenopausal weight loss"
- (Statement 4): "The first diet pill specifically designed for menopausal and perimenopausal women."
- (Statement 5): "Estrin-D™ helps overcome your physical and emotional changes."
- (Statement 6): "The first diet pill specifically designed developed to help menopausal and perimenopausal women lose weight."
- (Statement 7): "Estrin-D™ is clinically shown to increase resting metabolic rate, boost energy levels and increase stamina in menopausal and perimenopausal women."
- (Statement 8): "Estrin-D™ helps overcome your physical and emotional changes."
- (Statement 9): "The only diet pill diet pill designed to help menopausal and perimenopausal women lose weight."

The following summary identifies the dietary ingredient(s) or supplement(s) for which a statement has been made:

<u>Statement Number</u>	<u>Identity of Dietary Ingredient(s) or Supplement(s) that is the Subject of the Statement:</u>
1	Estrin-D™ – 120 ct. Box
2	Estrin-D™ – 120 ct. Box
3	Estrin-D™ – 120 ct. Box
4	Estrin-D™ – 120 ct. Box
5	Estrin-D™ – 120 ct. Box

90260

975 0162

LET 15012

6	Estrin-D™ – 120 ct. Box
7	Estrin-D™ – 120 ct. Box
8	Estrin-D™ – 120 ct. Box
9	Estrin-D™ – 120 ct. Box

The following identifies the brand name of each supplement for which a statement is made:

<u>Statement Number</u>	<u>Brand Name</u>	<u>Label or Labeling?</u>
1	Covaxil™ Laboratories, LLC	both
2	Covaxil™ Laboratories, LLC	both
3	Covaxil™ Laboratories, LLC	both
4	Covaxil™ Laboratories, LLC	both
5	Covaxil™ Laboratories, LLC	both
6	Covaxil™ Laboratories, LLC	both
7	Covaxil™ Laboratories, LLC	both
8	Covaxil™ Laboratories, LLC	both
9	Covaxil™ Laboratories, LLC	both

I, Joel Ehrenkranz, M.D., am authorized to certify this Notification on behalf of Covaxil™ Laboratories, LLC. I certify that the information presented and contained in this Notification is complete and accurate, and that Covaxil™ Laboratories, LLC has substantiation that each structure-function statement is truthful and not misleading.

Dated this 29 day of October, 2004.

By: N. Chevreau  
 Nathalie Chevreau PhD, RD  
 for Dr. Joel Erhankranz, MD  
 Consultant to Covaxil™ Laboratories, LLC

# EstrinD™

## EstrinD™

The first diet pill specifically designed  
for menopausal and perimenopausal women\*



- Raises resting metabolic rate in menopausal and perimenopausal women\*
- Boosts energy levels and increases stamina in menopausal and perimenopausal women\*
- Reduces diet fatigue associated with menopausal and perimenopausal weight loss\*

Dietary Supplement  
**120 capsules**

**COVAXIL™**  
LABORATORIES

### Supplement Facts\*\*

Serving Size: 2 capsules  
Servings Per Container: 60

	Amount Per Serving	% Daily Value†
Vitamin B6	25mg	1250%
Magnesium (as oxide)	100mg	25%
<b>Estrin-D™</b>	1323mg	
<b>a proprietary blend containing:</b>		
Yerbe Mate (leaf) SE***	†	
Caffeine	†	
Guarana (seed) SE***	†	
Damiana (leaf, stem) SE***	†	
Green Tea (leaf) SE***	†	
Ginger (root)	†	
Kola nut SE***	†	
DHEA	†	
Schisandra (fruit)	†	
Scutellaria (root) SE***	†	
Tibetan ginseng (root) SE***	†	
Cocoa nut SE***	†	
Jujube (fruit)	†	
Thea sinensis complex (leaf) SE***	†	

†Percent Daily Values are based on a 2,000 calorie diet  
† Daily Value not established

\*\*This product is manufactured to be within all acceptable industry variances

\*\*\*Standardized Extract (SE) means an extraction process providing the highest quality compound manufactured to acceptable industry variances

Distributed by:  
**Customer Service Distribution Center**  
Salt Lake City, UT 84116  
**1-800-898-5153**

Product resale allowed only through authorized representatives. International distribution not authorized without prior written approval.

Manufactured in the U.S.A.  
[www.EstrinD.com](http://www.EstrinD.com)

**Estrin-D™ Directions:** Take two capsules with a full glass of water, 15-30 minutes before main meals. Not to exceed 2 servings in any 8-hour period. Do not exceed 6 capsules per day.

# EstrinD™

**MENOPAUSE.** It's more than hot flashes and mood swings. It's about gaining weight. You exercise... you barely eat... and you still put on the pounds (in places you never gained weight before).

But now, there's Estrin-D™. The first diet pill specifically developed to help menopausal and perimenopausal women lose weight.\* Estrin-D is clinically shown to increase resting metabolic rate, boost energy levels and increase stamina in menopausal and perimenopausal women.\* Estrin-D helps overcome your physical and emotional changes.\* So, for the first time... in a long time... losing weight is easy.

Estrin-D will change your life. The only diet pill designed to help menopausal and perimenopausal women lose weight.\* Estrin-D. You'll lose weight. You'll love it!

**COVAXIL™**  
LABORATORIES

**NOTE:** For persons sensitive to the effects of xanthines (i.e., caffeine and caffeine-like stimulants), start by taking only 1 capsule and do not exceed a total of 2 capsules per day. Limit the use of caffeine-containing medications, foods or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness and occasionally, rapid heart beat. For additional information on this or any other Covaxil Laboratories™ product, please call our experienced customer service representatives at: 1-800-898-5153.

**WARNING:** This product contains a significantly potent xanthine (i.e., caffeine and caffeine-like stimulants) mixture, in excess of 300 mg per regular 2-capsule serving. Therefore, Estrin-D™ is not intended for use by pregnant or lactating women. Consult your physician before use, especially if you are sensitive to stimulants or occasional use only. Not intended for use by persons under 40 years of age. Do not use if you have a medical condition, or are taking prescription medications, without consulting your medical professional. If your health-care provider has any questions, ask him or her to call 1-800-898-5153.

Keep out of reach of children.

Use only as directed. Store at controlled room temperature 15°-30°C/59°-86°F.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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